United States Court of Federal Claims

No. 99-578 V
(Filed Under Seal: July 2, 2015)
(Reissued: July 27, 2015)[*]

JOSEPH MICHAEL D'ANGIOLINI,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

OPINION

Block, *Judge*.

The National Vaccine Injury Compensation Program (the "Program") was established by the National Vaccine Childhood Injury Act of 1986 in order to "achieve optimal prevention of human infectious diseases through immunization." 42 U.S.C. § 300aa-1. To this end, the Program provides compensation to individuals who can establish by a preponderance of the evidence that they have suffered "a vaccine-related injury."

Petitioner, Joseph D'Angiolini, filed a petition for compensation under the Program on August 4, 1999. In his petition, Mr. D'Angiolini alleged that he developed three medical conditions as a result of his hepatitis B vaccination: chronic fatigue syndrome ("CFS"), systemic lupus erythematosus ("SLE" or "lupus"), and autoimmune syndrome induced by adjuvants ("ASIA"). On March 27, 2014, Special Master Christian Moran denied Mr. D'Angiolini's petition on the grounds that Mr. D'Angiolini had failed to persuasively establish that he suffered from CFS and SLE. The Special Master also found that Mr. D'Angiolini had failed to establish that the ASIA condition can provide a reliable theory for recovery.

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[*] This opinion originally was issued under seal on July 2, 2015. The court afforded the parties an opportunity to propose redactions in the opinion prior to its reissue. No such redactions were proffered. Accordingly, herewith is the reissued opinion without redactions.

Petitioner advances numerous objections to the Special Master's decision. But, for the reasons explained below, the court rejects these arguments and will deny petitioner's motion for review of the decision.

I. BACKGROUND

A. Petitioner's Medical History

Petitioner was born on September 10, 1966. Dec. at 3. From an early age, he suffered from obsessive-compulsive disorder ("OCD"). Ex. 24 at 5-7. As petitioner reached age 20, his OCD worsened and he experienced headaches 3-4 times per week. Ex. 23 at 35-36, 56 at 2; Tr. 98. These symptoms were severe enough that they interfered with petitioner's personal relationships and led him to seek treatment for his OCD from both a psychologist, Nancy Casella, and a psychiatrist, Dr. Debra Roman. Findings of Fact at 15.

Despite his OCD, petitioner led an active life and maintained two jobs prior to his vaccination. Ex. 51 at 26; Tr. 93. He worked as a mental health technician at the Pottstown Medical Center and as a part-time music teacher at Bachman's Music Store. Tr. 150-51, 409-11; Ex. 16 at 296-301.

In March of 1997, petitioner changed jobs, accepting a mental health technician position at Valley Forge Medical Center. Ex. 51 at 190. As a condition of employment, petitioner was vaccinated for hepatitis B. Ex. 16 at 162, 233. He received the first of his three doses[1] on March 18, 1997. Ex. 16 at 162, 233. Following this first dose, petitioner continued to work at the Valley Forge Medical Center and Bachman's Music Store. Tr. 231-32; Ex. 16 at 304.

Several weeks later, on April 18, 1997, petitioner underwent a second round of vaccination. Ex. 16 at 162, 233. In early May, petitioner became concerned with his health. *Id.* Petitioner stated that he was sleeping 15 hours per day and experiencing migraine headaches. Ex. 24 at 11; Ex. 51 at 49, 193. By July 29, petitioner reported that he also was experiencing stuffiness due to a sinus infection. Ex. 61.

Roughly two months later, on October 6, petitioner visited a local physician, Dr. Harold Buttram. Ex. 17 at 125. Dr. Buttram diagnosed petitioner with chronic fatigue and myocarditis.[2] *Id.* Dr. Buttram stated that, petitioner had been in "excellent health" prior to his vaccination but was "badly crippled" after his second dose of the vaccine. *Id.* He concluded that a "causal relation of the hepatitis [vaccine] with his present myocarditis is highly probable." *Id.*

Four days later, on October 10, petitioner met with Dr. Gregory Bach, a physician board-certified in family and addiction medicines. Ex. 5 at 21. Dr. Bach noted that petitioner was complaining of "sweats, [weight] gain, stomach problems, heart palpitations, twitching

[1] As explained below, petitioner was administered the hepatitis B vaccine in three doses, the first on March 18, the second on April 18, 1997, and the third on October 24, 1997.

[2] Myocarditis is an inflammation of the myocardium, the middle, and thickest, layer of the heart wall. *Dorland's Illustrated Medical Dictionary* 1221 (32nd Ed. 2012).

headache, neck stiffness, light sensitivity, light head, confusion, difficulty with speech, mood swings, [and] depression." *Id.* Given the wide range of symptoms, Dr. Bach believed petitioner could be afflicted with fibromyalgia, chronic fatigue, or myopathy.[3] *Id.* at 26. Blood work and an echocardiogram ordered by Dr. Bach returned mostly normal results but did detect mild hypokinesis.[4]

On October 24, 1997, petitioner received his third round of vaccine injection. Ex. 16 at 162, 233. Eleven days later, on November 4, petitioner requested an emergency appointment with his psychiatrist, Dr. Middleman. At their session the next day, petitioner reported to Dr. Middleman that he was sleeping 12-15 hours per day, was not attending to his own personal hygiene, and had been soliciting prostitutes. Ex. 24 at 13.

One day later, petitioner began a leave of absence from his position at Valley Forge Medical Center. Ex. 16 at 118, 150. At this time, petitioner had also ceased teaching music at Bachman's Music Store. Ex. 51 at 18, 40. He was no longer shaving or showering and felt that he was physically and mentally unable to care for himself. Ex. 51 at 20-21.

Also on November 6, petitioner sought out Dr. Joshua Bray.[5] Dec. at 21. Dr. Bray is a general practitioner and not board-certified in any specialized field. Ex. 50 at 206. Petitioner and his mother describe Dr. Bray as a "country doctor." Tr. 491, 313. Dr. Bray's notes state that petitioner reported "extreme fear, feel[ing] immobilized, afraid to leave the house, [and] not caring for himself or his environment." Ex. 61. Dr. Bray did not conduct a physical examination of petitioner but believed that petitioner was suffering from severe depression, adjustment disorder, panic disorder, and agoraphobia. *Id.* Dr. Bray prescribed medication and penned a letter stating that petitioner was under treatment for "major depression" and was unable to work. Ex. 73 at 3.

On November 10, petitioner saw his psychiatrist, Dr. Roman. Ex. 23. During this visit, petitioner reported that he was experiencing headaches, nausea, depression, anxiety, and fatigue. *Id.* at 32. Dr. Roman referred petitioner to a cardiologist, Dr. Fredrick J. Weber. Petitioner stated that for the last year he had been experiencing "dyspnea on exertion when doing a strenuous exercise."[6] Ex. 6 at 17. Dr. Weber diagnosed petitioner with cardiomyopathy. Ex. 5 at 6.

Petitioner returned to Dr. Bray on November 13th. Dr. Bray's notes state that petitioner's condition had not improved. Ex. 61. Dr. Bray again commented that petitioner was suffering from major depression and panic disorder and could not work. Ex. 73 at 1.

Next, petitioner visited the Penn Center for Healing on November 17, complaining of fatigue. His attending physician, Dr. Anne Norris, noted that petitioner had "been out of work

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[3] Fibromyalgia is characterized by pain and stiffness in the muscles and joints. *Dorland's Illustrated Medical Dictionary* 703 (32nd ed. 2012). Myopathy refers to muscle disease. *Id.* at 1224.

[4] Hypokinesis is defined by decreased mobility, motor function, or activity. *Dorland's Illustrated Medical Dictionary* 903 (32nd ed. 2012).

[5] Dr. Bray had previously treated petitioner on July 29th for a sinus infection. Findings of Fact at 27.

[6] Dyspnea is "shortness of breath." *Dorland's Illustrated Medical Dictionary* 582 (32nd ed. 2012).

for a year" due to fatigue. Ex. 22. Dr. Norris found that petitioner did not get refreshing sleep and suffered from headaches. *Id.* at 4. Notably, Dr. Norris did not diagnose petitioner with chronic fatigue syndrome, finding that petitioner's condition did not meet the criteria of CFS. *Id.*

On November 30, Dr. Bray wrote a second letter on behalf of petitioner's disability benefit claim. Ex. 17 at 15. In this letter, Dr. Bray stated that petitioner was originally placed on disability due to depression and that petitioner suffers from CFS. *Id.* Dr. Bray concluded that petitioner's CFS rendered him "not able to work in any capacity." *Id.*

Dr. Bray referred petitioner to Dr. Burton A. Waisbren, a physician board-certified in internal medicine. Ex. 50 at 8. Dr. Waisbren has remarked that patients often seek his opinion because he has openly expressed his belief that hepatitis B vaccine can cause autoimmune diseases. Ex. 50 at 13-17. Dr. Waisbren reviewed petitioner's medical history and stated that petitioner suffered from worsening malaise and fatigue after his vaccination doses, culminating in a year-long fugue after the third dose. Ex. 17 at 37. Dr. Waisbren also conducted a physical exam and concluded that petitioner was suffering from vaccinal encephalomyelitis and a general autoimmunity condition. *Id.*at 39. He also proposed a "hypothetical analysis" of Root-Bernstein syndrome. *Id.* at 41.

On December 15, Dr. Bray endorsed petitioner's application for disability benefits. Ex. 16 at 145-46. Dr. Bray stated that petitioner's symptoms were "crying, [inability] to stay awake, not caring for self, shortness of breath, dizziness, heart rac[ing], chest pain, extreme fear, feel[ing] immobilized, [and] afraid to go out." *Id.* On January 22, 1998, Dr. Bray wrote a letter in support of petitioner's disability claim that restates the contents of his November 6 and November 13 notes and letters. Ex. 73 at 2. Dr. Bray's next set of notes, dated February 12, 1998, state that petitioner was experiencing "severe anxiety and increased symptoms." Ex. 61.

Petitioner continued to visit his psychiatrist, Dr. Roman, and his psychologist, Nancy Casella, who each diagnosed him with OCD, anxiety, and depression. Ex. 24 at 15, 17; ex. 61 at 1; Tr. 45-49. Ms. Casella also diagnosed him with adjustment disorder, depressed mood, panic disorder, and severe agoraphobia. Ex. 16 at 111. On petitioner's disability benefits form, Ms. Casella attested that petitioner was unable to work and that his home environment, with his parents, was volatile. *Id.*

Petitioner returned to Dr. Bray in February of 2000. Ex. 17 at 159. On February 22, 2000, Dr. Bray penned a letter on behalf of petitioner summarizing his condition from 1997 onward. *Id.* at 109-10. In his letter, Dr. Bray recorded that in June of 1997, petitioner was afflicted with "extreme fatigue, chest pain, palpitations, [shortness of breath] with exertion, nausea, diaphoresis, aches and pains," and memory/cognitive issues. *Id.*

Dr. Bray stated that these symptoms were continuing to worsen at that time. *Id.* Dr. Bray's letter recounted that, by October 26, 1997, petitioner's condition had degraded and his symptoms had become more dramatic; petitioner "was sleeping all the time, felt as though his heart was pounding through his chest, had extreme chest pain, shortness of breath, diaphoresis, felt as though he would pass out, [and] his joints and muscles ached." *Id.* Dr. Bray diagnosed petitioner with "Systemic Autoimmune Disease, Cardiomyopathy, Post Encephalomyelitis, Depression secondary to chronic illness and limitations/changes in lifestyle due to illness." *Id.* Dr. Bray also listed more than 20 "subjective symptoms" and "objective clinical findings." *Id.*

On March 2, 2000, petitioner visited Dr. Joseph Bellanti, an immunologist. Ex. 3. Dr. Bellanti recounted that, within 24 hours of receiving the first dose of hepatitis B vaccine, petitioner "developed symptoms of malaise, muscle and joint pains, headaches and an overall 'flu-like' syndrome." *Id.* He expressed a strong suspicion that "there is a causal relationship between the hepatitis B vaccination which [petitioner] received and the symptoms which he is undergoing." *Id.* at 2.

Several days later, petitioner lost consciousness while walking and sustained a thumb fracture. Ex. 13 at 8-9. During his recovery, petitioner met with Dr. Scott Fried. Ex. 19 at 3. Dr. Fried stated that, prior to his thumb injury, petitioner was "playing the guitar for a number of hours at a time and also the piano," observing that "[h]e is really not limited in any activities." *Id.*

On September 29, 2000, petitioner visited Dr. Frank Vasey, a rheumatologist at the University of South Florida, College of Medicine. Ex. 133 at 18. Dr. Vasey recorded that petitioner was in good health prior to the first dose of vaccination but, after receiving that dose, "developed promptly some headaches and flu-like symptoms." *Id.* Dr. Vasey documented petitioner's recollection that, following the third dose of the vaccine, petitioner "had another reaction with chest pain, shortness of breath, sweats and worsening of his flu-like symptoms." *Id.* At the time of his visit, petitioner reported that he was experiencing "chronic fatigue, muscle and joint pain." *Id.* Dr. Vasey believed petitioner was experiencing "an immune reaction to hepatitis B vaccination . . . complicated by chronic fatigue and fibromyalgia." *Id.* But, Dr. Vasey conceded that because recognition of this problem was at a "case report level . . . honest physicians could contest [his] opinion." Ex. 133 at 23.

Dr. Bray wrote another letter on May 9, 2002, summarizing petitioner's treatment under Doctors Bach, Norris, Weber, Buttram, Waisbren, Bellanti, Vasey, and others. Ex. 131. Dr. Bray wrote that petitioner "clearly meets" the criteria for Systemic Lupus Erythematosus of the American College of Rheumatology and restated his diagnoses from previous letters, including cardiomyopathy, post encephalomyelitis, neuropathy, and depression. *Id.*

On June 3, 2003, petitioner met with Dr. Harold Pretorius, who administered a single-photo emission computed tomography scan of petitioner's brain. Ex. 40 at 4-10. Dr. Pretorius found indicia of "nonspecific neurodegeneration." *Id.* at 3. Dr. Pretorius believed that petitioner's results might indicate petitioner was suffering from "[l]upus-like cerebritis." *Id.* at 2

Almost thirteen months later, on June 30, 2004, petitioner visited a neurologist, Dr. Maurice Hanson, at a Cleveland Clinic in Naples, Florida. Ex. 37. Dr. Hanson reviewed petitioner's medical records and concluded that they contained "conflicting data" and "many interpretations" which were in need of clarification. *Id.* at 24. On Dr. Hanson's recommendation, petitioner underwent a neuropsychology evaluation, the results of which, in Dr. Hanson's opinion, "did not document any evidence of psychosis or a psychiatric disorder." *Id.* at 25. Dr. Hanson referred petitioner to a specialist in infectious diseases, Dr. Margaret J. Gorensek.

Dr. Gorsensek reviewed petitioner's medical record and concurred with Dr. Hanson's observation that petitioner's medical history was convoluted. Ex. 37 at 21. Dr. Gorsensek opined that "the patient [has] had so many evaluations, so many differing opinions, that there is no one

consistent opinion." *Id.* Dr. Gorensek concluded that these divergent diagnoses make it "more suspicious that there really is not any significant opinion." *Id.*

On October 19, 2004, Dr. Hanson saw petitioner on an emergency basis, due to severe headaches. *Id.* Dr. Hanson's examination of petitioner was "essentially normal," but he noted that petitioner had been diagnosed with cardiomyopathy. *Id.* at 26-7. Dr. Hanson referred petitioner to a cardiologist, Dr. Galatro, who diagnosed petitioner with lupus. *Id.* Petitioner visited Dr. Hanson again on November 19, 2004, and Dr. Hanson stated that he concurred with Dr. Galatro's diagnosis that "this is an autoimmune disorder which falls presume[ably] into the lupus category." *Id.* at 25. Petitioner returned to Dr. Galatro on June 22, 2005. *Id.* at 20. At that time, Dr. Galatro noted petitioner's medical history included "chronic fatigue syndrome, SLE, and cardiomyopathy." *Id.* She diagnosed petitioner with cardiomyopathy and SLE but not chronic fatigue syndrome. *Id.* Subsequently, petitioner has continued to seek treatment from Dr. Vasey roughly twice a year. Tr. 693; Ex. 133 at 1-15.

B. The Special Master's Decision

On March 27, 2014, the Special Master issued a decision denying compensation under the Vaccine Act, on the ground that petitioner failed to establish any of the three alleged "vaccine-related injur[ies]." In the first place, the Special Master found that petitioner had failed to establish by preponderant evidence that he actually suffered from CFS. Likewise, the Special Master determined that petitioner had failed to establish, by a preponderance of the evidence, that he actually suffered from SLE. Finally, the Special Master determined that ASIA, the third condition alleged by petitioner, did not provide a medically reliable theory for compensation.

Chronic Fatigue Syndrome

The first condition that the Special Master adjudicated was chronic fatigue syndrome. CFS is a condition characterized by a primary symptom of persistent fatigue, accompanied by ancillary symptoms. *Dorland's* at 359, 685, 1819; Tr. 728, 1157-60. The fatigue must be "persistent or relapsing [and] lasting 6 or more consecutive months" and cause "substantial reduction in previous levels of occupational, educational, social, or personal activities." Exhibit U (Keiji Fukuda et al., The Chronic Fatigue Syndrome: A Comprehensive Approach to Its Definition and Study, 121 ANN. INTERN. MED. 953 (1994)) at 953). Additionally, CFS requires four or more of the following eight ancillary symptoms to be concurrently present for more than 6 months: (i) impaired memory or concentration, (ii) sore throat, (iii) tender cervical or axillary lymph nodes, (iv) muscle pain, (v) multi-joint pain, (vi) new headaches, (vii) unrefreshing sleep, or (viii) post-exertion malaise. *Id.* at 955. Notably, "[i]t is difficult to interpret symptoms typical of the CFS in the setting of illnesses such as major psychotic depression." Ex. U at 957. For that reason, the Fukuda standards exclude patients with "[a]ny past or current diagnosis of a major depressive disorder with psychotic or melancholic features" from CFS diagnosis. *Id.* at 955.

The Special Master stated that evaluating petitioner's fatigue was "challenging," given the nearly 15-year period that had elapsed between petitioner's vaccination and the Special Master's decision. Dec. at 56. As a result, the Special Master emphasized the petitioner's employment history. *Id.* at 57-60. The Special Master found petitioner's employment records to be the most reliable evidence of petitioner's condition because "unlike the [medical] record, which depends largely on the historian's ability to recall what happened, Mr. D'Angiolini's employment records are objective." *Id.* at 58.

The Special Master found that these records demonstrated that petitioner was continuing to work two jobs until November 5, 1997. *Id.* at 58. At this point, the Special Master stated that petitioner's employment underwent a "sudden reduction" but that the "reason for the decrease in activities is not entirely clear." *Id.* According to the Special Master, the notes of petitioner's psychiatrist reflect that petitioner was experiencing suicidal thoughts, visiting prostitutes, and was struggling to maintain personal hygiene, but did not mention fatigue. The Special Master pointed out that Dr. Bray notes from November 6, 1997, also do not mention fatigue. *Id.*

The Special Master highlighted what he termed a "confounding piece of evidence," the medical report from petitioner's April 1998 emergency room visit. Dec. at 58; Ex. 15. The Special Master determined that petitioner's statements to ER physicians that he jogged and was otherwise "active" contradicted the assertion that petitioner was suffering from persistent fatigue. *Id.* In view of Dr. Shoenfeld's testimony describing the extreme severity of fatigue associated with CFS, the Special Master found this statement "tantamount to a concession that Mr. D'Angiolini was not suffering from chronic fatigue." Dec. at 59. The Special Master also recounted petitioner's medical history, finding that it did not persuasively establish persistent fatigue. Dec. 59-60.

The Special Master also found that petitioner had not established that he suffered from 4 or more of the 8 Fukuda ancillary symptoms for over 6 months. Dec. at 60-65. The Special Master found that only three of these symptoms, post-exertional malaise, muscle pain, and joint pain, were plausibly supported by the record. *Id.* He ruled out three symptoms, impaired memory, unrefreshing sleep, and headaches, because petitioner had experienced them prior to his vaccination. He also opined that two other symptoms, sore throat and tender lymph nodes, were not sufficiently proven by the evidence. *Id.* Accordingly, the Special Master concluded petitioner had not demonstrated that he suffered from CFS.

The Special Master noted that under the precedents of the Court of Appeals for the Federal Circuit ("Federal Circuit"), petitioner's "failure to present preponderant evidence that he suffers from CFS precludes an award of compensation based upon this disease." Dec. at 65 (citing *Broekelschen v. Sec'y of Dep't of Health & Human Servs*., 618 F.3d 1339, 1350 (Fed. Cir. 2010) and *Lombardi v. Sec'y of Health and Human Servs*., 656 F.3d 1343, 1352 (Fed. Cir. 2011)). Nonetheless, as an alternate ground for his decision, the special master proceeded to apply the *Althen* test for determining whether the vaccination was the cause-in-fact of the alleged condition. *See Althen v. Sec'y of Health & Human Servs*., 418 F.3d 1274, 1278 (Fed. Cir. 2005). The Special Master found that petitioner failed to satisfy the *Althen* test. Dec. at 65-74.

Lupus

The second condition the Special Master reviewed was Systemic lupus erythematosus, better known as lupus. Lupus is an autoimmune disease[7] that can affect many body systems, including joints, heart, and skin. Tr. 1128. The American College of Rheumatologists first laid out the guidelines for lupus, dubbed the "Tan criteria," in 1982. Ex. T (Eng M. Tan et al., The 1982 Revised Criteria for the Classification of Systemic Lupus Erythematosus, 25. The criteria

[7] Auto immune conditions are "characterized by a specific humoral or cell-mediated immune response against constituents of the body's own issues." *Dorlands* at 181.

were revised in 1997. Exhibit L (1997 Update of the 1982 American College of Rheumatology Revised Criteria for Classification of Systemic Lupus Erythematosus (1997)).

The record contains discordant medical opinions on whether petitioner was afflicted with lupus. The Special Master evaluated the opinions of seven physicians: Vasey, Bray, Hanson, Galatro, Pretorius, Shoenfeld, and Lightfoot. Dec. at 77-82. Five believed that petitioner suffered from lupus: Bray, Hanson, Dr. Galatro, Dr. Pretorious, and Dr. Shoenfeld. *Id.* Dr. Vasey and Dr. Lightfoot were of the opinion that petitioner did not have lupus. *Id.*

The Special Master found Dr. Vasey's opinion that petitioner did not suffer from lupus to be the most persuasive. *Id.* In the Special Master's view, Dr. Vasey's specialized training as a board-certified rheumatologist and experience treating lupus patients made him exceptionally credible. Dec. at 77. The Special Master also lent weight to Dr. Vasey's extensive, over-a-decade-long history of treating petitioner. *Id.* The Special Master remarked that "the possibility that Mr. D'Angiolini suffered from lupus was such a remote possibility that it 'never . . . crossed [Dr. Vasey's] mind." The Special Master weighed Dr. Vasey and Dr. Lightfoot's opinions against Doctors Bray, Hanson, Galatro, Pretorius, and Shoenfeld's and found Dr. Vasey's to be more persuasive.

The Special Master evaluated and discussed ten of the eleven Tan diagnostic criteria for lupus: complement blood levels,[8] DNA antibodies, serositis,[9] seizures or psychosis, arthritis, malar rash,[10] oral ulcers, renal disorder,[11] photosensitivity, and presence of antinuclear antibodies. Of these criteria, the Special Master found that two provided some evidence that petitioner was afflicted with lupus: DNA testing and arthritis. The Special Master chose not to consider the evidence on complement levels, considering it "out-of-date" because the most recent diagnostic criteria do not consider complement levels as a factor in diagnosis. Dec. at 83. The Special Master determined the seven remaining factors either did not indicate lupus or militated against a finding of lupus. Dec. at 82-92. Specifically, he found that the lack of malar rash and lack of antinuclear antibodies "effectively undercut" Dr. Shoenfeld's position that petitioner had lupus. Dec. at 93. Further, the Special Master believed that "Dr. Shoenfeld stretched and pulled the diagnostic criteria well past a reasonable point." *Id.*

Auto Immune Syndrome Induced by Adjuvants

The final condition evaluated by the Special Master was Autoimmune Syndrome Induced by Adjuvants,[12] or ASIA. As mentioned above, the Special Master acknowledged that Dr. Shoenfeld is arguably the foremost expert on ASIA. Dec. at 94. He has been one of the chief

[8] Complement refers to protein levels in petitioner's blood. *Dorlands* at 393.

[9] Serositis is "inflammation of the serous membrane." *Dorlands* at 1698. The Tan criteria define serositis as "Pleuritis --convincing history of pleuritic pain or rub heard by a physician or evidence of pleural effusion OR Pericarditis---documented by ECG or rub or evidence of pericardial effusion." Ex. T at 1274.

[10] Malar rash is a facial rash typical of lupus. Ex. T at 1274; Tr. 884.

[11] Renal disorders are kidney conditions defined by the Tan criteria as "a) Persistent proteinuria greater than 0.5 grams per day or greater than 3+ if quantitation not pe[r]formed OR b) Cellular casts -- may be red cell, hemoglobin, granular, tubular, or mixed." Ex. T at 1274.

[12] An adjuvant is "a nonspecific stimulator of the immune response." *Dorland's Illustrated Medical Dictionary* 32 (32nd Ed. 2012)

contributors the medical research on the condition and, as the Special Master commented, Dr. Shoenfeld "contributed to the genesis of ASIA." *Id.*

Dr. Shoenfeld has proposed the following major criteria for ASIA: exposure to a stimulus (e.g., a vaccine) appearance of clinical manifestations (such as myalgia, myositis, muscle weakness, arthritis, chronic fatigue, unrefreshing sleep, sleep disturbances, or neurological issues), cognitive impairment/memory issues, dry mouth/pyrexia, improvement after removal of inciting agent, and biopsy of involved organs. Ex. 88 at 4. He has suggested the following minor criteria for ASIA: appearance of autoantibodies, other clinical manifestations, specific human leukocyte antigens, and evolvement of an autoimmune disease. Dr. Shoenfeld has written that "to diagnose ASIA, fulfillment of either two major or one major and two minor criteria is required." Ex. 189A (Y. Zafir et al., Autoimmunity following Hepatitis B vaccine as part of the spectrum of 'Autoimmune (Auto-inflammatory) Syndrome induced by Adjuvants' (ASIA): analysis of 93 cases, 21 Lupus 146 (2012)) at 150; accord Tr. 925-26.

But, as Dr. Shoenfeld acknowledged, research on ASIA is ongoing and "in about a year or two when we will revise all the criteri[a], . . . we will add many details . . . when we accumulate more experience and more cases." Tr. 920; Tr. 1471 (Dr. Shoenfeld stating that "[w]e may add [factors], we may detract, and so forth."). Dr. Lightfoot underscored the uncertainty surrounding ASIA's diagnostic criteria, calling it "a very interesting hypothesis that needs to be developed." Tr. 1175.

The Special Master found that the ongoing discovery and definition of the ASIA condition was problematic. Dec. at 100. He described the ASIA theory as "like a sapling" and concluded that it was not far along enough in its growth to provide a basis for recovery. *Id.* The Special Master referenced "many examples of where [Dr. Lightfoot] saw a lack of precision in the proposed diagnostic criteria. Dec. at 97. In Dr. Lightfoot's view, the criteria "are sufficiently ill-defined currently that is makes it very difficult to . . . make the diagnoses." Tr. 1174. The Special Master placed particular emphasis on Dr. Lightfoot's testimony that the ASIA criteria, as currently constituted, cannot support accurate diagnoses. Dec. at 98.

The Special Master was persuaded by Dr. Lightfoot's view and determined that "Dr. Shoenfeld [had] not made a persuasive case that ASIA is a legitimate and generally accepted medical condition." Dec. at 98. For that reason, the Special determined the ASIA theory could not provide petitioner with a basis for recovery.

In sum, the Special Master denied petitioner's alleged CFS, SLE, and ASIA claims. He determined that petitioner did not suffer from CFS and SLE and that the ASIA condition did not provide a basis for recovery. Accordingly, he determined that petitioner was not entitled to compensation under the Vaccine Act.

II. STANDARD OF REVIEW FOR VACCINE ACT CASES

The Court of Federal Claims has jurisdiction to review the decision of a special master in a Vaccine Act case upon a properly filed petition for review. 42 U.S.C. § 300aa—12(e)(1). When reviewing a special master's decision, the court must take one of the following three courses of action:

a. Uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

b. Set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

c. Remand the petition to the special master for further action in accordance with the court's decision.

42 U.S.C. § 300aa–12(e)(2).

In conducting its review, the court applies different standards to conclusions of law, findings of fact, and discretionary rulings. *Masias v. Sec'y of Health & Human Servs*., 634 F.3d 1283, 1287-88 (Fed. Cir. 2011)[13] (construing 42 U.S.C. § 300aa–12(e)(2)(B)); *see also Munn v. Sec'y of Dep't of Health & Human Servs*., 970 F.2d 863, 871 no. 10 (Fed. Cir. 1992); *Pafford v. Sec'y of Health and Human Servs*., 64 Fed. Cl. 19, 27 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006).

The court reviews conclusions of law, such as conclusions regarding legal standards and burdens of proof, under the "not in accordance with law standard." *Doe v. Sec'y of Health & Human Servs*., 98 Fed. Cl. 553, 566 (2011). Under this standard, a Special Master's application of the law is not entitled to deference. *Jarvis v. Sec'y of Health and Human Servs.*, 99 Fed. Cl. 47, 58 (2011); see also *Althen*, 418 F.3d at 1278–79; *Saunders v. Sec'y of Dep't of Health & Human Servs*., 25 F.3d 1031, 1033 (Fed. Cir. 1994) ("Because [the special master's award of attorneys' fees] is a legal question, we apply the "not in accordance with law" standard. Thus, we review the special master's award *de novo* . . .").

A Special Master's findings of fact are reviewed under the arbitrary and capricious standard, which is "well understood to be the most deferential [standard] possible." *Munn*, 970 F.2d at 870. "Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims." *Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs*., 717 F.3d 1363, 1366 (Fed. Cir. 2013) (quoting *Hodges v. Sec'y of Dept. of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993) (internal citations omitted)). It is not the role of this court to "reweigh the factual evidence," "assess whether the special master correctly evaluated the evidence," or "examine the probative value of the evidence or the credibility of the witnesses." *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2010). "If the special master 'has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate.'" *Hibbard v. Sec'y of Health & Human Servs*., 698 F.3d at 1363 (quoting *Hines on Behalf of Sevier v. Sec'y of Dep't of Health & Human* Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991)). In other words, the court is "not to second guess [a] [s]pecial [m]aster's fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process." *Hodges*, 9 F.3d at 961.

The court reviews a special master's discretionary rulings under the "abuse of discretion" standard. *Munn*, 970 F.2d at 870 n. 10. Such rulings typically include review of evidentiary

[13] "Under the Vaccine Act, [the Federal Circuit] review[s] a decision of the special master under the same standard as the Court of Federal Claims." *Masias*., 634 F.3d at 1287.

rulings. *See, e.g. Piscopo v. Sec'y of Health & Human Servs*. 66 Fed. Cl. 49, 53 (2005). "An abuse of discretion may be found when (1) the court's decision is clearly unreasonable, arbitrary, or fanciful; (2) the decision is based on an erroneous conclusion of the law; (3) the court's findings are clearly erroneous; or (4) the record contains no evidence upon which the court rationally could have based its decision." *Hendler v. United States*, 952 F.2d 1364, 1380 (Fed. Cir. 1991); *Woods v. Sec'y of Health & Human Servs*., 105 Fed. Cl. 148, 151 (2012).

III. DISCUSSION

A. The Vaccine Act

The Vaccine Act, 42 U.S.C. §§ 300aa–1 to –34, established the National Vaccine Injury Compensation Program to compensate individuals injured by vaccines "quickly, easily, and with certainty and generosity." H.R. Rep. No. 99–908, at 6 (1986), 1986 U.S.C.C.A.N. at 6344. The Vaccine Act allows petitioners to seek compensation if they have "sustained, or ha[ve] significantly aggravated" any "illness, disability, injury, or condition" caused by a vaccine (*i.e.*, "vaccine-related"). 42 U.S.C. § 300a-11(c)(1)(C).

The Act provides petitioners two avenues for obtaining compensation: "table" and "off-table" claims. *W.C. Sec'y of Health & Human Servs*., 704 F.3d 1352, 1355 (Fed. Cir. 2013). For table claims, if the petitioner can demonstrate that they received a vaccine listed in the Vaccine Injury Table and that they suffered an injury within the time period laid out by the table, the petitioner "benefits from a statutory presumption of causation." *Id*. Petitioners whose injuries do not coincide with the Vaccine Injury Table, referred to as "off-table" claims, must establish actual causation "by a preponderance of the evidence." *Id*.; 42 U.S.C. § 300aa-13(a)(1). Stated another way, a petitioner making an off-table claim must present evidence showing that the vaccine "more likely than not" caused the injury. *Capizzano v. Sec'y of Health & Human Servs*., 440 F.3d 1317, 1326 (Fed. Cir. 2006). The case at bar presents "off-table" claims.

The Special Master must also consider whether a petitioner suffered from the alleged injury. Although the Vaccine Act does not require absolute precision, it does require the petitioner to establish an injury—the Act specifically creates a claim for compensation for "*vaccine-related* injury or death." 42 U.S.C. § 300aa-11(c) (emphasis added). "The function of a special master is not to 'diagnose' vaccine-related injuries, but instead to determine based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused [petitioner's] injury." *Lombardi*, 656 F.3d at 1352-53 (quoting *Andreu ex rel. Andreu v. Sec'y of Dep't of Health & Human Servs*., 569 F.3d 1367, 1382 (Fed. Cir. 2009)); *see also Broekelschen*, 618 F.3d at 1349 (Fed. Cir. 2010). As the Federal Circuit has remarked:

> [i]f a special master can determine that a petitioner did not suffer the injury that she claims was caused by the vaccine, there is no reason why the special master should be required to undertake and answer the separate (and frequently more difficult) question whether there is a medical theory, supported by "reputable medical or scientific explanation," by which a vaccine can cause the kind of injury that the petitioner claims to have suffered.

Hibbard, 698 F.3d at 1365. It is "appropriate for the Special Master to first determine what injury, if any, was supported by the evidence in the record before applying the *Althen* test to determine causation. In the absence of *any* specific injury of which petitioner complains, the question of causation is not reached." *Lombardi*, 656 F.3d at 1352-53 (emphasis added) (internal citations removed).

Once an injury has been established, the petitioner has the burden of satisfying the following three-prong test set forth in *Althen v. Sec'y of Health & Human Servs*.:

> Concisely stated, [petitioner's] burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury. If [petitioner] satisfies this burden, she is entitled to recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine.

418 F.3d 1274, 1278 (Fed. Cir. 2005). The Federal Circuit emphasized in *Althen* that the Vaccine Act does not require exact or conclusive evidence of causation, but a medically credible theory coupled with evidence of a proximate temporal and causal relationship between the injury and the vaccination. *See Althen*, 418 F.3d at 1281-1282 (stating that "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body").

B. Review of the Special Master's Decision

Petitioner enumerates five objections to the Special Master's decision. Pet'r's Mot. at 2-3. First, petitioner argues that the Special Master required petitioner "to prove an elevated evidentiary burden expressly rejected in *Althen*, which was not in accordance with the law." *Id.* at 2. Second, petitioner contends that the Special Master "fail[ed] to consider relevant evidence and deliberately omitted other relevant evidence." *Id.* Third, petitioner argues that the Special Master "abused his discretion by rejecting Dr. Shoenfeld's testimony that the Hepatitis B vaccine can cause CFS, SLE, and ASIA. *Id.* Fourth, petitioner asserts that the Special Master abused his discretion by rejecting Dr. Shoenfeld's testimony on the *Althen* prongs. And finally, petitioner contends that the Special Master "utilized the pretense of 'persuasiveness' regarding petitioner's expert . . . in order to manufacture a basis to reject petitioner's evidence of causation." *Id.* at 2-3.

1. **The Special Master Did Not Impose a Heightened Evidentiary Burden**

Petitioner argues that the Special Master imposed an "elevated evidentiary burden" on petitioner's claims by requiring petitioner "[to] identify[] the specific cause or causes of CFS." Pet'r's Mot. at 12. Petitioner argues that this approach is contrary to Circuit precedent established in the *Knudson* and *Althen* cases. Pet'r's Mot. at 13-14. Since this argument challenges a legal conclusion by the Special Master, the applicable standard of review is the "not in accordance with the law" standard. *See Doe*, 98 Fed. Cl. at 566. But for the reasons that follow, the court finds it unnecessary to reach a conclusion as to this objection.

In both *Knudson* and *Althen*, the Federal Circuit considered what standard is appropriate for determining whether a petitioner with an off-table claim has met his burden of showing, by a preponderance of the evidence, the existence of a causal relationship between the vaccination and petitioner's condition. In *Knudson*, the Federal Circuit stated that "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program" and that the court is "not to be seen as a vehicle for ascertaining precisely how and why . . . vaccines sometimes destroy the health and lives of [patients] . . . ." *Knudson v. Sec'y HHS*, 35 F.3d 543, 549 (Fed. Cir. 1994). Concordantly, the Federal Circuit remarked, in *Althen*, that the purpose of the preponderance standard in vaccine cases "is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." *Althen*, 418 F.3d at 1280.

In effect, Petitioner's objection, that the Special Master improperly applied an "elevated burden" by requiring "identification and proof of specific biological mechanisms" for showing that the hepatitis B vaccination can cause CFS, is a challenge to the Special Master's application of the *Althen* test for causation-in-fact. But as the court explained above, Federal Circuit precedent provides that the Special Master need not apply the *Althen* prongs if the Special Master determines that the petitioner does not suffer from the alleged condition. *See, e.g.*, *Lombardi*, 656 F.3d at 1352-53, *Broekelschen*, 618 F.3d at 1349, *Hibbard*, 698 F.3d at 1365.

Lombardi is particularly analogous to the case at bar. Also a hepatitis B vaccine case, the petitioner in *Lombardi* claimed CFS and SLE injuries, relying on Dr. Shoenfeld as an expert witness. *Lombardi*, 656 F.3d at 1354-56. In *Lombardi*, as in the instant case, there was remarkable dissonance among the examining physicians about the nature of petitioner's injury. *Id*. In that case, the Special Master concluded that petitioner did not suffer the alleged injuries and accordingly declined to apply the *Althen* test to determine if the petitioner had met his burden of establishing causation by a preponderance of evidence. The petitioner in *Lombardi*, like Mr. D'Angiolini, argued that this approach "imposed on her an improper burden of proving a diagnosis with scientific certainty even before she could prove causation under *Althen*." *Lombardi* 656 F.3d at 1352.

The Federal Circuit rejected this position, stating that "if the existence and nature of the injury itself is in dispute, it is the special master's duty to first determine which injury was best supported by the evidence presented in the record before applying the *Althen* test to determine causation of that injury." *Id.* (citing *Broekelschen*, 618 F.3d at 1346). The *Lombardi* court commented that it "in the absence of *any* specific injury of which petitioner complains, the question of causation is not reached." *Lombardi*, 656 F.3d at 1352-53 (emphasis added) (internal citations removed). The Federal Circuit expounded on this view in *Hibbard*, commenting that:

> [i]f a special master can determine that a petitioner did not suffer the injury that she claims was caused by the vaccine, there is no reason why the special master should be required to undertake and answer the separate (and frequently more difficult) question whether there is a medical theory, supported by "reputable medical or scientific explanation," by which a vaccine can cause the kind of injury that the petitioner claims to have suffered.

Hibbard, 698 F.3d at 1365. This court has consistently applied Federal Circuit precedent in cases similar to the one at bar. *See e.g., Simanski v. Sec'y of Health & Human Servs.*, 115 Fed.

Cl. 407, 452 (2014) *aff'd sub nom*, *Simanski v. Dep't of Health & Human Servs.*, 601 F. App'x 982 (Fed. Cir. 2015), *Stillwell v. Sec'y of Health & Human Servs.*, 118 Fed. Cl. 47 (2014) *aff'd*, No. 2015-5005, 2015 WL 3650794 (Fed. Cir. June 15, 2015), *Dillon v. Sec'y of Health & Human Servs.*, 114 Fed. Cl. 236 (2014).

As explained above, the Special Master in this case determined that petitioner—like the petitioner in *Lombardi*—failed to establish by preponderant evidence that he actually suffered from either CFS or SLE. Therefore, petitioner's "heightened evidentiary burden" objection is irrelevant unless petitioner can demonstrate that the Special Master erred in making this factual finding.

In reviewing findings of fact, the court applies the arbitrary and capricious standard. *See Doe*, 98 Fed. Cl. at 566. The role of the court is not to "reweigh the factual evidence." *See Deribeaux*, 717 F.3d at 1366. "If the special master 'has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate.'" *Hibbard*, 698 F.3d at 1363 (quoting, *Hines*, 940 F.2d at 1528). The court finds that the Special Master comprehensively analyzed the petitioner's evidence in accordance with the diagnostic and ancillary criteria set forth by Fukuda,[14] examining the evidence presented for each of the Fukuda factors over the course of twelve pages of his decision. Dec. at 53-65. The Special Master's thorough analysis of the evidence lead him to conclude that petitioner had failed "to present preponderant evidence that he suffers from CFS." *Id*. In light of petitioner's failure to establish by preponderant evidence that he actually suffered from CFS or SLE, "the question of causation" addressed by the *Althen* Test "is not reached." *Lombardi*, 656 F.3d at 1352-53.

For the foregoing reasons, the court finds that the Special Master did not act arbitrarily and capriciously in determining that petitioner does not suffer from CFS or SLE. Accordingly, the court does not reach petitioner's objection that the Special Master improperly applied the *Althen* test by using a "heightened evidentiary burden."

2. **The Record Does Not Demonstrate that the Special Master Failed to Consider, or Improperly Considered, Relevant Evidence**

Petitioner makes the vague assertion that the Special Master abused his discretion by "failing to consider relevant evidence and deliberately omit[ing] other relevant evidence." Pet'r's Mot. at 2. Notably, petitioner does not identify specific evidence that the Special Master ignored or omitted.

Instead, petitioner argues that "in reaching his conclusion that [petitioner] did not suffer from CFS, the Special Master had to ignore or disregard his own findings of fact." Pet'r's Mot. at 13. In essence, petitioner contends that even though the Special Master considered the pertinent facts, he erred because his conclusion runs counter to the evidence in the record that petitioner had CFS. In petitioner's view, "the record is indisputable" that petitioner was afflicted with CFS because some of petitioner's examining physicians diagnosed him with CFS. Pet'r's Mot. at 14.

[14] As explained above, the parties both employ a set of diagnostic criteria referred to as the Fukuda criteria. Keiji Fukuda et al., The Chronic Fatigue Syndrome: A Comprehensive Approach to Its Definition and Study, 121 Ann. Intern. Med. 953 (1994)) at 953); Ex. U.

But the mere presence of some "contrary evidence" does not necessarily upset the Special Master's finding that the "record as a whole" indicated petitioner did not suffer from CFS. *Doe v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1358 (Fed. Cir. 2010); 42 U.S.C. § 300aa–13(a). Here, the Special Master conducted an extensive analysis of the evidence in the record on petitioner's CFS claim, applying the Fukuda primary and ancillary diagnostic criteria. Dec. at 56-66.

The Special Master determined that petitioner did not suffer from persistent fatigue, the primary criterion for CFS, because his employment history demonstrated that he remained active, working two jobs until November 5, 1997. *Id*. at 58. The Special Master found petitioner's employment history to be the most reliable evidence because "unlike the [medical] record, which depends largely on the historian's ability to recall what happened, Mr. D'Angiolini's employment records are objective." *Id.* at 58. Furthermore, the Special Master examined each of the eight ancillary symptoms and determined that only three were plausibly supported by the record. Dec. at 60-65. He ruled out the remaining five symptoms either because petitioner had experienced them prior to vaccination or failed to demonstrate them. *Id.*

Similarly, the record does not reveal any mistreatment of the facts by the Special Master on lupus. The Special Master provided a thorough analysis of the facts in the record in relation to the Tan diagnostic criteria for lupus, devoting over eleven pages of his opinion, and determined that, on balance, they did not indicate that petitioner was afflicted with the condition. Dec. at 82-93. The primary reason for the difference of opinion between the Special Master and petitioner was the weight that the Special Master lent to the report and testimony of petitioner's treating physician and expert witness, Dr. Vasey.

The Special Master found Dr. Vasey's opinion very persuasive because of Dr. Vasey's volume of experience[15] with lupus in his practice as a board-certified rheumatologist, as well as Dr. Vasey's experience treating the petitioner. Dec. at 93. In the Special Master's view, Dr. Vasey "was capable of diagnosing lupus and had more than a decade to see signs and symptoms of lupus" in the petitioner. Dec. at 93. The Special Master found Dr. Vasey's statement that the possibility of lupus "never really crossed [his] mind" particularly persuasive, in light of the fact that Dr. Vasey had attended to the patient for over twelve years. Dec. at 79; Tr. at 1574.

Furthermore, the Special Master was skeptical of petitioner's claim that seven of the Tan criteria were satisfied. The Special Master objected to Dr. Shoenfeld's "broaden[ing]," "stretching," and "blurring" of the serositis, neurological, and arthritis factors, respectively. Dec. 85, 86, 88. The Special Master rejected Dr. Shoenfeld's testimony on these factors as not credible. *Id.*

In sum, the court disagrees with plaintiff's contention that the Special Master abused his discretion by disregarding or omitting facts. This court's role is "not to second guess" a special master's "fact-intensive conclusions" and the court declines to do so here. *Hodges*, 9 F.3d at 961.

[15] Over the course of his career, Dr. Vasey has treated over 100 lupus patients. Dec. at 77; Tr. 1568.

3. **The Special Master Did Not Improperly Reject Dr. Shoenfeld's Testimony on Whether the Vaccine Can Cause CFS, SLE, and ASIA**

Petitioner contends that the Special Master abused his discretion by rejecting Dr. Shoenfeld's testimony that the Hepatitis B vaccine can cause CFS, SLE, and ASIA. The court disagrees. In the first place, the Special Master found that petitioner failed to establish that petitioner suffered from either CFS or SLE, and only addressed the matter of causation as an alternative ground for his decision. Because the court will not disturb the Special Master's findings that petitioner did not suffer from CFS or SLE, Dr. Shoenfeld's testimony on those issues is irrelevant. Dr. Shoenfeld's testimony on the ASIA condition, however, is relevant because the basis for the Special Master's decision on petitioner's ASIA claim was that ASIA did not provide a biologically plausible theory connecting the vaccine and injury.

Petitioner relies heavily on Dr. Shoenfeld's testimony as "the world's pre-imminent expert in autoimmunity" to prove causation and legitimize the ASIA condition. Petitioner contends that although ASIA "is a novel syndrome discovered by Dr. Shoenfeld, it continues to gain acceptance in the autoimmune scientific community" and should be considered as an accepted medical condition. Pet'r's Mot. at 20, 27. Petitioner contends that "a medical theory propounded by medical experts with highly relevant academic credentials and specific field expertise is prima facie evidence of biological plausibility. . . ." *Althen*, 418 F.3d at 1278.

The Special Master rejected ASIA as a basis for recovery despite Dr. Shoenfeld's testimony because he found that research on ASIA is still developing and currently incomplete. Dec. at 99. For that reason, the Special Master found that ASIA "does not have sufficient current support to be a reliable basis for compensation in the Vaccine Program." *Id.*

In reaching this conclusion, the Special Master closely examined Dr. Shoenfeld's published work in conjunction with his testimony on ASIA, as well as numerous articles on the subject by other researchers. *Id.* at 95-98 (discussing Yehuda Shoenfeld and Nancy Agmon-Levin, 'ASIA' – Autoimmune/inflammatory syndrome induced by adjuvants, 36(1) J. Autoimmunity 1 (2011)) and Y. Zafir et al., Autoimmunity following Hepatitis B vaccine as part of the spectrum of 'Autoimmune (Auto-inflammatory) Syndrome induced by Adjuvants' (ASIA): analysis of 93 cases, 21 Lupus 146 (2012)). The Special Master determined, on the basis of these articles, that the criteria for ASIA were still in development. Dec at 96 (finding that "Dr. Shoenfeld was open to expanding the list of external stimuli" and "the initial paper did not specify how the criteria related to the diagnosis."). The Special Master also highlighted Dr. Shoenfeld's statements that "[t]here might be additional stimuli which we still did not define" and "in about a year or two when we will revise all the criteri[a], . . . we will add many details . . . when we accumulate more experience and more cases." Tr. 905; 920.

The Special Master was persuaded by testimony from Dr. Lightfoot that the ASIA criteria "was an initial attempt to sort of corral this concept." Tr. 1181. The Special Master highlighted Dr. Lightfoot's doubt that "this criteria set is sharp and crisp enough to say, okay, now we can really tell this syndrome from normal people." *Id.* The Special Master was swayed by Dr. Lightfoot's "many examples of where he saw a lack of precision in the proposed diagnostic criteria." Dec. at 97. The Special Master found Dr. Lightfoot's opinion that the criteria "are sufficiently ill-defined currently that it makes it very difficult to . . . make [a] diagnosis" very persuasive. Tr. 1174. The Special Master also pointed to Dr. Vasey's testimony that ASIA is still "a new and novel concept that, you know, really should be tested out logically." Tr. 1555.

In the Special Master view, petitioner "failed to establish that Dr. Shoenfeld's opinion regarding ASIA meets the minimum threshold for reliability." Dec. at 100 (citing *Moberly*, 592 F.3d at 1324). Critically, he found that ASIA's "diagnostic criteria do not differentiate between healthy and ill people." *Id*. The Special Master described the ASIA theory as "like a sapling" in need of "maturation" before it can be considered "a reliable construct." Dec. at 99.

The court rejects petitioner's argument that the Special Master improperly disregarded Dr. Shoenfeld's testimony and upholds the Special Master's determination that the ASIA condition did not provide a reliable theory for recovery. As the Federal Circuit has observed, "[m]edical recognition of the injury claimed is critical." *Broekelschen*, 618 F.3d at 1349. Although "general acceptance in the scientific or medical communities" is not required, a medical theory "must be supported by a sound and reliable medical or scientific explanation." *Andreu*, 569 F.3d at 1378; *Knudsen*, 35 F.3d at 548. It is within the ambit of a special master's authority to reject a petitioner's theory. *See e.g., Porter*, 663 F.3d at 1253-54; *Moberly*, 592 F.3d at 1322; *Broekelschen*, 618 F.3d at 1350-51.

The Special Master did not err by examining the conflicting expert testimony on petitioner's medical theory and determining that ASIA does not provides a biologically plausible theory for recovery. The Special Master based his decision on testimony that ASIA's criteria were changing and imprecise and that, as currently formulated, ASIA's criteria cannot distinguish between afflicted and un-afflicted patients. The Special Master's determination that this evidence undercut the reliability of the condition as a sufficient basis for compensation under the Program was not arbitrary or capricious.

4. **The Special Master Did Not Improperly Reject Dr. Shoenfeld's testimony on the *Althen* prongs**

As explained above, the Special Master applied the *Althen* test in the alternative. Since the court upholds the Special Master's determination that petitioner did not suffer from either CFS or SLE, Dr. Shoenfeld's testimony on the *Althen* prongs is irrelevant.

5. **The Special Master Did Not Improperly Weigh Expert Testimony**

Petitioner argues, in general terms, that the Special Master "utilized the pretense of 'persuasiveness' regarding petitioner's expert . . . in order to manufacture a basis to reject petitioner's evidence of causation." *Id.* at 2-3. But petitioner does not present any specific evidence to undermine the Special Master's determinations on the expert witnesses' persuasiveness.

Special masters are charged with assessing the reliability of evidence before them and, accordingly, are not "precluded from inquiring into the reliability of testimony from expert witnesses." *Moberly*, 592 F.3d at 1324; *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed.Cir.1999) ("[T]he rules of evidence require that the trial judge determine whether the testimony has a reliable basis in the knowledge and experience of the relevant discipline.").

In the case at bar, the Special Master's persuasiveness determinations are grounded in the record. The Special Master found that Dr. Vasey's testimony on petitioner's lupus claim was more persuasive then Dr. Shoenfeld because of Dr. Vasey's vast experience with lupus. Dec. at 93. The Special Master determined that Dr. Lightfoot's testimony on the problems with defining

the ASIA condition was persuasive, despite Dr. Shoenfeld's illustrious qualifications. The record reflects that the Special Master carefully weighed each of the experts' testimony and does not demonstrate that his decision was arbitrary or capricious.

IV. CONCLUSION

In sum, the court upholds the Special Master's determination that petitioner has failed to prove, by a preponderance of the evidence, that he suffers from a vaccine-related injury. Accordingly, the Special Master's **DECISION** to deny petitioner's claim is **AFFIRMED** and petitioner's **MOTION** for review of that decision is **DENIED**.

IT IS SO ORDERED.

s/ Lawrence J. Block
Lawrence J. Block
Judge